

DIAPHRAGM

I. INTRODUCTION

The contraceptive diaphragm is a dome-shaped latex or silicone device that serves as a mechanical barrier against the cervix and holds a spermicidal preparation in place within the vagina. The diaphragm is one of the oldest contraceptive methods, is non-hormonal, and easy to use. There are currently two different diaphragms on the market, 1) the traditional one that needs to be fitted by a health care provider and 2) the newly approved Caya diaphragm that is specially shaped so it comes in one size that fits most women.

Efficacy with perfect use results per 6 pregnancies in 100 users per year—versus 16 pregnancies per 100 users per year with typical use.

II. CLIENT SELECTION

- A. Indications – The diaphragm may be an appropriate method of contraception for women who:
 - 1. Prefer an intercourse-related non-hormonal method of contraception.
 - 2. Desire a barrier method that can provide continuous protection for up to 24 hours.
- B. Contraindications – (USMEC 3-- Risks outweigh advantages for method use; USMEC 4--Unacceptable risk for method use):
 - 1. History of toxic shock syndrome (TSS) (USMEC 3).
 - 2. Allergy to product components including allergy to spermicides (USMEC 3).
 - 3. High Risk for HIV/AIDS (USMEC 4) - due to concerns related to the spermicide and not the diaphragm itself. Repeated and high-dose use of the spermicide nonoxynol-9 was associated with increased risk for genital lesions, which might increase the risk for HIV infection.
 - 4. HIV/AIDS (USMEC 3) – Use of spermicides or diaphragms (with spermicide) can disrupt the cervical mucosa, which might increase viral shedding and HIV transmission to non-infected sex partners
 - 5. Antiretroviral (ARV) (USMEC 3) – not a drug interaction related to diaphragm itself but categorization related to contraindication for use of spermicide in presence of HIV or risk for HIV

III. MANAGEMENT OF WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

Consultation with site Medical Director should occur before providing a diaphragm to clients in any of the following situations:

- A. Less than 3 months since cervical surgery (including colposcopy with biopsy cryotherapy, LEEP, laser therapy, or knife cone biopsy).
- B. Less than 2 weeks since mid-trimester abortion or less than 6 weeks post-partum.
- C. Recent history of frequent lower urinary tract infections, especially if associated with prior diaphragm use.

IV. MEDICAL SCREENING, FITTING AND EVALUATION

- A. Comprehensive medical evaluation (history, physical examination and laboratory testing as indicated) should be completed prior to provision of a diaphragm.
- B. Diaphragm Fitting:
 - 1. Traditional diaphragms come in different sizes (50mm to 95 mm in diameter) and in different types (e.g. coil spring, flat spring, and arcing spring). The arcing spring type is designed to be inserted without a special inserter.
 - 2. The diaphragm should fit comfortably with the anterior rim lodged behind the pubic bone and the posterior rim seated deep in the posterior vaginal fornix.
 - 3. The largest, most comfortable diaphragm that fits well should be chosen. It is essential to involve the patient in the evaluation of the fit of her diaphragm. She should be asked to offer her impression of how easy or difficult removal is for each size, and if two diaphragms fit equally well, which one feels more comfortable.
 - 4. The Caya diaphragm comes in only one-size that fits nearly all women. Women who have been previously fit for a diaphragm 65, 70, 75 or 80 mm can use Caya without a fitting. Women who have never used a diaphragm should have a fitting to ensure their comfort in the use of a diaphragm and for the provider to evaluate the fit (single use test fit units are available to providers free of charge at <http://caya.us.com/services/for-providers/>)
 - 5. Following fitting of the diaphragm, sufficient time should be provided for the patient to practice insertion and removal during the office visit.
 - 6. Use of a back-up method of contraception until the return visit, or until the patient is sure that the diaphragm is staying in place during intercourse should be advised.
 - 7. Women need to receive instruction on the use of spermicide
- C. Guidelines for cleaning and disinfection of fitting sets must be followed (See package insert in fitting set).
- D. Delayed Exam
 - 1. Physical exam and related preventative services should not be deferred beyond 3 months after the initial visit and may not be deferred beyond 6 months (unless there is a compelling reason for extending the deferral in the clinician's judgment).
 - 2. The reason for the deferral of pelvic exam must be documented in the client's medical record.
 - 3. A complete history, height, weight and BP is required in the medical record.
 - 4. Written results of a physical exam done by another provider within the last 12 months are acceptable.
 - 5. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- E. Pap test screening protocols for the site must be followed.

V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a diaphragm should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to diaphragms, including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues
- C. Instruction on care of diaphragm (cleaning and inspection) and on the use of non-oil based lubricants with latex diaphragms and water-based lubricants only with Caya (which is non-compatible with silicone-based lubricants).
- D. Information that the diaphragm may provide only limited protection against STIs/HIV
- E. Method specific informed consent
- F. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- G. Written and verbal instruction on method use (may use Package Insert) which should include the following:
 - 1. Insertion procedure including the application of spermicide
 - 2. Instruction on how to determine proper placement of diaphragm
 - 3. Instruction on need to leave diaphragm in place for at least six hours after last act of intercourse.
 - 4. Instruction on need to insert additional spermicide without if six hours have lapsed since time of insertion as well as for each subsequent act of intercourse irrespective of time lapse.
 - 5. Recommendation to avoid leaving diaphragm in place for more than 24 hours in order to decrease risk of toxic shock syndrome
- H. Upon request, a copy of the method specific consent form
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained
- J. Clinic access information

VI. PRESCRIBING DIAPHRAGM

Both traditional diaphragms and Caya single-size diaphragm require a provider prescription. Traditional diaphragms require a specification of diaphragm type and size. The clinician will determine the appropriate diaphragm size after examining the client and fitting for size. Clients can obtain Caya on line through the manufacturer's website.

VII. MANAGEMENT OF SIDE-EFFECTS AND COMPLICATIONS

- A. Recurrent vaginal or introital irritation, with no evidence of vaginal infection, may indicate an allergy or sensitivity to spermicide, latex, or silicone.
- B. Recurrent UTIs – assess for appropriate fit. Consider method change if fit appropriate and UTIs are still an issue
- C. Toxic Shock Syndrome (TSS) signs or symptoms require urgent and intensive evaluation and treatment.
- D. Because TSS risk is increased for a woman who has had TSS in the past, women with a history of TSS should avoid use of vaginal barrier methods. After STD treatment, the Caya diaphragm should be exchanged for a new device per manufactures instructions.

VIII. FOLLOW-UP

- A. The diaphragm user should be advised to return (at each of these visits diaphragm fit should be reassessed):
 - 1. In 2-3 weeks for a re-check of diaphragm fit, to evaluate placement skills and to screen for possible problems.
 - 2. Annually, or more often as requested by the client.
- B. Diaphragm fit also should be reevaluated in the case of:
 - 1. Frequent dislodgment.
 - 2. Vaginal or lower abdominal discomfort coincident with diaphragm use.
 - 3. Full-term pregnancy.
 - 4. Pregnancy termination after the first trimester.
 - 5. Pelvic surgery.
 - 6. Recurrent lower urinary tract infection.
 - 7. Weight gain or loss of 10 pounds or more.
 - 8. The Caya diaphragm should be exchanged for a new device every 2 years

IX. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.
- B. Diaphragms dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

REFERENCES

- 1. Medical Eligibility Criteria for Contraceptive Use. MMWR / July 29, 2016 / Vol. 65 / No. 3
- 2. Hatcher, R., et. Al. Contraceptive Technology. 20th Edition, 2011.